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09/864,488	05/24/2001	Marcia A. Wise	7733.D2	3552

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06/06/2003

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EXAMINER

SIRMONS, KEVIN C

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/864,488

Applicant(s)

WISE ET AL.

Examiner

Kevin C. Simons

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56,59-66,68-72 and 74 is/are pending in the application.
- 4a) Of the above claim(s) 55,57,58,67 and 73 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 64 is/are allowed.
- 6) ☒ Claim(s) 56,59-62,65,66,68-72 and 74 is/are rejected.
- 7) ☒ Claim(s) 63 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election of Species I in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Note: Applicant has withdrawn claims 67 and 73.

Claims 55, 57 and 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement, however, applicant failed to properly traverse the restriction requirement by not submitting evidence or identifying such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case in Paper No. 5.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 60 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 60 and 61 recites the limitation "the act of purging". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 56, 65, 66, 68 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Kipperman U.S. Pat. No. 5,092,839.

Kipperman discloses in combination, a catheter tube (11) comprising a hollow unobstructed passageway (interior of (11)), and a balloon (14) positionable within the unobstructed passageway (figs. 2-14) and selectively inflated to span across the entire passageway to close, seal and completely occlude all of the hollow passageway at the distal end of the catheter tube against entry of blood (figs. 3, 7 and 14) when flow is not occurring through the hollow passageway (fig. 3, 7 and 14); as to claim 65, see above rejection; as to claim 66, (13/16); as to claim 68, (9, col. 3, lines 39-45); as to claim 69; (the manifold 6 has a port which can be used to flush liquid (col. 3, lines 30-45).

Note: the device of Kipperman is fully capable of selective liquid flow therethrough to or from a patient during aspiration and/or irrigation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 70-72 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipperman U.S. Pat. No. 5,092,839.

Kipperman discloses a catheter substantially as claimed except or companion ingress and egress side-by-side non-concentric catheter tubes. (Applicant is merely attempting to claim two of the identical aforementioned tubes not having a common center). It would have been obvious to one of ordinary skill in the art at the time the invention was made to duplicate the device of Kipperman, since it has been held that mere duplication of essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, USPQ 8; as to claim 71, (14/16, the examiner regards the hollow tube (13/16) as the stem); as to claim 72, (9, col. 3, lines 39-45); as to claim 74, (the manifold 6 has a port which can be used to flush liquid (col. 3, lines 30-45).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 3763

Claim 59 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,364,867. Although the conflicting claims are not identical, they are not patentably distinct from each other because is substantially claiming similar subject matter such as the method of addressing the problem of clotting in one or more tube indwelling within a vessel of a patient.

As to claim 59 of the application and 7 of the patent, claim 59 discloses the method substantially as claimed except for the purging of the lumen.

Claims 59, 62 and 70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-6 and 13 of U.S. Patent No. 6,270,489. Although the conflicting claims are not identical, they are not patentably distinct from each other because is substantially claiming similar subject matter such as the method of addressing the problem of clotting in one or more tube indwelling within a vessel of a patient.

As to claim 59 of the application and 4 of the patent, claim 59 discloses the method substantially as claimed and additionally includes the purging of the hollow interior.

As to claims 59 and 62 of the application and 5 of the patent, claim 59 discloses the method substantially as claimed and 62 of the application include deflating both balloons. The difference between claims 59 and 62 of the application and 5 of the patent is the additional limitation of a slit valve in claim 5 of the patent.

As to claim 59 of the application and 6 of the patent, claim 6 discloses the method substantially as claimed except for explicitly stating a position at least partially radially within and blood infiltration and clotting.

Art Unit: 3763

It is the examiners position that advancing a deflated balloon along an entirely hollow and unobstructed lumen of each ingress and egress catheter tube essentially includes a position at least partially radially within a distal end of each. In addition, the preamble of claim 6 of the patent is addressing the problem of clotting, therefore, blood infiltration and clotting will be prevented in the lumen as taught in the application.

As to claim 70 of the application and 13 of the patent, both claims are fundamentally/structurally the same except for non-influential changes in the language of the claims.

Allowable Subject Matter

Claims 63 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 60 and 61 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: As to claim 60, the prior art of record discloses the method substantially as claimed except for purging the hollow interior of one or both catheter tubes in a proximal-to-distal direction with a suitable liquid under pressure **prior to the inflation act.**

As to claim 61, the prior art of record discloses the method substantially as claimed except for the pressure of the purging liquid temporarily deforming and unsealing the inflated balloon.

Art Unit: 3763

As to claim 63, the prior art of record discloses the method substantially as claimed except for withdrawing the balloons along the lumens of the catheter tubes after the deflating act and before the causing act.

Claim 64 is allowable over the prior art of record.

The following is an examiner's statement of reasons for allowance: as to claim 64, the prior art of record does not disclose withdrawing the balloon from association with the catheter tube after the deflating act and before the causing act.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is 903-306-5410. The examiner can normally be reached Monday-Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

KCS
6/2/03